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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,522	09/22/2003	Andre Stamm	31672-224622	5813

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
03/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/665,522	**Applicant(s)** STAMM ET AL.	
	Examiner Humera N. Sheikh	**Art Unit** 1615	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 February 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *16 February 2010*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *none*.
   Claim(s) objected to: *none*.
   Claim(s) rejected: *16,18-20,36 and 41-45*.
   Claim(s) withdrawn from consideration: *6,7,13,14,25-33,38,39 and 46-48*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615

Continuation of 11. does NOT place the application in condition for allowance because:
Applicant argues that their "improved bioavailability of their composition is based on a novel process" or their fenofibrate processing techniques. Namely, Applicant argues that their fluid-bed granulation techniques attribute to enhanced bioavailability of the formulation. This argument was not deemed persuasive. The instant claims are drawn to a fenofibrate product and not a process of manufacturing fenofibrate. It is the patentability of the product that must be established and not the manner by which bioavailability is achieved (such as by specific manufacturing processes - i.e.., fluid bed granulation). Thus, Applicant's arguments drawn to the advantages of the manufacturing process are not commensurate in scope with the instant product claims. In any event, the prior art teaches fenofibrate products having increased or improved bioavailability. The art further recognizes using low dosages of fenofibrate (200 mg) to achieve therapeutic effects (i.e., bioavailability).

Applicant argues, "Krause compositions may comprise from 300 to 1200 mg of fenofibrate. Krause tablets are at best bioequivalent to Lipanthyl®300, the first generation of fenofibrate drugs. Krause tablets are not bioequivalent to Lipanthyl®200M, let alone superior to them." These arguments were not found persuasive. While it is noted that the Krause compositions may comprise from 300 to 1200 mg of fenofibrate, and not a daily dose of 'lower than 200 rag', the secondary reference of Deboeck was relied upon for the teaching of fenofibrate compositions whereby the fenofibrate ranges from about 100 mg to 600 mg per day, and preferably from about 100 to 300 mg per day (see col. 8, lines 18- 24). Deboeck further teaches that their pharmaceutical compositions offer increased bioavailability of the fenofibrate as compared to conventional formulations (col. 3, lines 36-38). Thus, Deboeck was invoked for and amply demonstrates using lower dosages of fenofibrate to obtain therapeutic and beneficial results, such as enhanced bioavailability. The prior art vividly teaches fenofibrate compositions having improved bioavailability; the same objective as that desired by Applicant.

Regarding the rejection of Ghebre-Sellassie (US '639) in view of Krause and Deboeck, Applicant argued, "Ghebre-Sellassie is directed to gemfibrozil, where the tablet has both an immediate release fraction and a sustained release fraction, obtained by two different granulations". Applicant's arguments were not found persuasive. Admittedly, while Ghebre-Sellassie is directed to gemfibrozil, the secondary reference of Krause was relied upon for the teaching of compositions comprising fenofibrate or alternatively gemfibrozil. The argument that Ghebre-Sellassie's tablet has both an immediate release part and a sustained release part in it was not convincing, since the instant claims do not exclude the sustained release portion of Ghebre-Sellassie. The instant claims permit the controlled release portion of the prior art.

Regarding Deboeck, Applicant argued, "Deboeck is directed to fenofibrate composition, specifically to a generic of Lipanthyl®200M". Thus, Deboeck discloses a composition having the same bioavailability as Lipanthyl®200M". Deboeck is directed to capsules and not to a tablet." These arguments were not deemed persuasive. Deboeck explicitly teaches fenofibrate formulations having increased bioavailability of fenofibrate as compared to conventional formulations. See for instance, Deboeck col. 3, lines 36-38. The art further teaches bioavailability parameters (AUC, Cmax, Tmax) and teaches suitable bioavailability levels as that instantly desired by Applicant (see Table 4 of Deboeck at column 8). It is noted that Deboeck is drawn to fenofibrate capsules and not tablets. However, the primary reference of Krause initially recognizes and teaches various forms of fenofibrate formulations, including both capsules and tablets. See col. 5, lines 12-20 of Krause. Thus, the art is aware of the array of dosage forms available, particularly tablets.

Applicant argued, "The invention is directed to a composition which has a bioavailability that is greater than that of Lipanthyl®200M. Krause and Ghebre-Sellassie provide tablets having a bioavailability that is lesser than that of Lipanthyl®200M.
Deboeck provides capsules having the same bioavailability as Lipanthyl®200M. Thus,none of the documents, either individually or in combination render the instant invention obvious."
Applicant's arguments were not held persuasive. Applicant attributes improved bioavailability of their composition based on their process of manufacturing fenofibrate and directs the Examiner to Table 3 of the specification and Figure 1. The argument of improved bioavailability over that of Lipanthyl®200M was not convincing since the claims are generic in scope as compared to that with the particular examples of the specification. The enhanced bioavailability particularly of Example 3 on page 12 occurs as a result of the specific bioavailability parameters (AUC, Cmax, Tmax). However, the instant claims are entirely generic in this regard. The instant claims do not introduce any specific dissolution profiles, rates of release, nor any specific AUC, Cmax, Tmax levels, which would distinguish over the teachings of the prior art. The claims are silent in terms of these specific features. Thus, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., improved bioavailability as a result of the specific AUC, Cmax, Tmax) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

Lastly, Applicant argued, "The Guichard document should be considered. Surprisingly, the invention demonstrates that it is further possible to increase the bioavailability of fenofibrate compositions". This argument was not held persuasive. The art in combination achieves fenofibrate formulations having increased bioavailability, which is the same objective sought herein by Applicant. As a result, the teachings of the prior art in combination, are sufficient to render the instant invention prima facie obvious to one of ordinary skill in the art.